

### **REMARKS**

By way of summary, independent claims 18, 20, 24, 28, 31, 35 and 36 have been amended and claims 29 and 30 have been canceled. Claims 1-17 and 37 were previously canceled. Accordingly, claims 18-28 and 31-36 are currently pending. No new matter has been added by way of this Amendment.

#### **Gelbfish - U.S. Patent No. 5,800,457**

Claims 18, 19, 22, 23, 29-31, 34 and 36 were rejected under 35 USC 102(b) as being anticipated by Gelbfish. Claims 20, 21, 24-28, 32, 33 and 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gelbfish in view of other references. Gelbfish teaches an intravascularly deployable device having an expandable filter body. The expandable filter body may be configured as a permanent vascular filter or as a temporary vascular filter. In either case, Gelbfish teaches a vascular filter device that is provided with an access port such that a cutting element can temporarily traverse the access port to remove debris from the filter body.

In contrast to Gelbfish, Applicant teaches an implantable vascular filter which includes an implantable agitation member. The implantable agitation member is permanently coupled to a filter body and the entire structure is configured to be implanted within a blood vessel. Applicant's implantable vascular filter makes it possible for the captured particles to be broken into smaller pieces without advancing a separate cutting tool into the filter body. There is no teaching or suggestion in Gelbfish regarding an implantable agitation member coupled to an implantable filter body.

In another preferred embodiment, Applicant teaches a thrombus removal system which can be temporarily advanced into a blood vessel. The thrombus removal system includes a filter body which is permanently fixed to a distal end of an outer catheter. A rotatable agitation member is longitudinally fixed to a distal end of an inner catheter. The agitation member is configured for longitudinal advancement out of the filter body for breaking apart a thrombus distal to the filter body. The filter body is configured to capture and hold the resulting particles as the filter body is withdrawn into the aspiration catheter for removal of the particles from the body.

Gelbfish provides no teaching or suggestion regarding a thrombus removal system having a filter body adapted to capture and hold debris. Furthermore, there is no teaching in Gelbfish regarding a thrombus removal system which further includes a rotatable agitation member which is longitudinally advanceable out of the filter body for breaking apart a thrombus.

### **Claim Amendments**

Independent claims 18, 31 and 36 have been amended to further distinguish over Gelbfish.

Independent claim 18 now recites an implantable vascular filter, comprising “an *implantable filter body* having a substantially conical shape, the filter body configured to be expanded and secured to an inner wall of a blood vessel” and “an *implantable agitation member* movably coupled to the filter body.” Claim 18 further recites that “the filter body and the agitation member are detachable from a delivery catheter for implantation in the blood vessel.” As discussed above, there is no teaching in Gelbfish regarding an implantable agitation member that is movably coupled to an implantable filter body. Similarly, there is no teaching in Gelbfish of a filter body and agitation member that are both detachable from a delivery catheter for implantation in a blood vessel.

Claims 19-30 depend from independent claim 18. Claims 20, 22 and 24 recite specific mechanisms for powering the implantable agitation member. With respect to claim 20, the structure noted by the Examiner in Demarais et al. is a helical wire which forms an “Archimedes screw.” The helical wire is rotated to pull particles through the lumen of a catheter. The helical wire disclosed by Demarais et al. is not shaped to be powered by the flow of blood through the blood vessel. Rather, the helical wire is merely a thin wire rotated by an external source. In contrast to the structure disclosed by Demarais et al., Applicant teaches a flow-receiving member which provides a power source for rotating the implantable agitation member. The flow-receiving member taught by Applicant is similar to a windmill which converts a moving fluid into mechanical energy. To further clarify that the flow-receiving member comprises a portion of the implantable device, Applicant has amended claim 20 to recite “an *implantable flow-receiving member* coupled to the agitation member.” In another

embodiment, dependent claim 22 recites that the implantable agitation member is adapted to be powered by an elongate drive mechanism which is configured for removable attachment to the agitation member. In another embodiment, dependent claim 24 recites that the implantable agitation member may be powered by an implantable energy device *directly coupled* to the filter body.

Independent claim 31 has been amended to clarify that the agitation member forms a portion of the implantable filter device. Claim 31 now recites “an agitation member located substantially within an interior volume of the filter body, *the agitation member permanently coupled to the filter body.*” Claim 31 further recites that “*the filter body and agitation member are detachable from a delivery catheter for fixation in the blood vessel* and wherein the agitation member is configured to macerate emboli captured within the filter body. Claim 32-35 recite specific drive mechanisms for powering the agitation member.

Independent claim 36 is directed to a device which may be temporarily advanced into a blood vessel for removing a thrombus. Claim 36 now recites a *thrombus removal system* configured to improve blood flow through a blood vessel, comprising a filter body *permanently fixed* to a distal end portion of an outer catheter, *the outer catheter having a length for extending from a location outside the body to a treatment site in a blood vessel*, the filter body configured to *capture and hold embolic particles*, the filter body having a *flexible membrane supported by a plurality of stiff members* and wherein the stiff members are biased to hold the filter body open in an unconstrained condition.

There is no teaching in Gelbfish of a thrombus removal system. There is no teaching in Gelbfish of an outer catheter having a filter body permanently fixed along a distal end portion. There is no teaching in Gelbfish regarding a filter body configured to capture and hold embolic particles that have broken loose from the treatment site. There is no teaching in Gelbfish of a filter body formed of a flexible membrane supported by stiff members wherein the stiff members are biased in an open position.

Independent claim 36 also recites “a *rotatable agitation member* permanently fixed to a distal end portion of an inner catheter, *the inner catheter being centrally disposed within the outer catheter* such that the filter body *provides a centering mechanism* for the agitation member and wherein the agitation member is rotatably and slidably coupled to the filter body.”

Gelbfish fails to disclose a rotatable agitation member mounted on an inner catheter which is centrally disposed within an outer catheter and wherein a filter body centers the agitation member.

Independent claim 36 also now recites “an aspiration catheter sized for slidable advancement over the outer catheter, the aspiration catheter configured for applying a negative pressure in the *annular region between an outer wall of the outer catheter and an inner wall of the aspiration catheter* for drawing particles from the blood vessel into the filter body.” Gelbfish fails to disclose an aspiration catheter for providing negative pressure in the annular region between the outer catheter and the aspiration catheter.

Independent claim 36 also now recites that “the rotatable agitation member is longitudinally advanceable to a location *distal to the filter body* for breaking apart a thrombus located distal to the filter body and wherein the filter body is configured to collapse into the aspiration catheter for withdrawing captured particles from the blood vessel *while captured particles are contained within the filter body*.” Gelbfish fails to disclose a system wherein a rotatable agitation member is advanceable beyond the filter body for treating a thrombus and wherein the filter body captures and holds particles such that the particles can be withdrawn from the blood vessel while contained within the filter body. The system recited in claim 36 is particularly advantageous because aspiration need only occur long enough to draw particles into the filter body. The captured particles are removed from the blood vessel by collapsing the filter body into the lumen of the aspiration catheter and then withdrawing the entire system from the patient while captured particles are contained in the filter body.

#### **Fees Due to File This Amendment**

Prior to the pending Office Action, a fee was paid for 20 claims, with 3 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the number of claims originally paid for, and thus no claim fees are believed to be due to file this amendment.

**Conclusion**

Should the Examiner have any remaining questions, the Examiner is encouraged to contact the Applicant at the telephone number shown below.

Date: \_\_\_\_\_

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Respectfully submitted,



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